- (i) the first level is similar or different from a baseline level determined in a control population of patients unaffected by the lysosomal storage disorder;
- (ii) the <u>first</u> level is an indicator of presence or extent of the <u>lysosomal storage</u> disorder in the patient;
 - (iii) the first saposin comprises saposin A, saposin B, saposin C, saposin D, prosaposin, mRNA encoding prosaposin, or a combination thereof; and (iv) the first sample is a plasma, serum, whole blood, urine, or amniotic fluid sample.
- 2. (Amended) The method of claim 1, wherein the first tissue-sample is a plasma sample.
- 3. (Amended) The method of claim 1, wherein the first tissue sample is a whole blood sample.
- 4. (Amended) The method of claim 1, wherein a presence of the lysosomal disorder in the patient, is indicated by the measured first level exceeds exceeding the baseline level. a mean level in a control population of individuals not having a the lysosomal storage disorder, to indicate presence of the disorder in the patient.
- 5. (Amended) The method of claim 1, further comprising:

measuring the <u>a second</u> level of the at least one saposin in a second tissue sample from the patient, the first and second samples being obtained at different times; and

comparing the <u>first level and the second level</u> levels in the samples to <u>indicate</u> monitor progression of the disease.

wherein,

- (i) the second saposin comprises saposin A, saposin B, saposin C, saposin D prosaposin, mRNA encoding prosaposin, or a combination thereof;
 (ii) the comparison of the first level and the second is an indicator of the
- (iii) the second sample is a plasma, serum, whole blood, urine, or amniotic fluid sample.
- 6. (Original) The method of claim 1, wherein the patient is undergoing treatment for the lysosomal storage disorder.

progression of the disease in the patient; and

- 7. (Amended) The method of claim 4, wherein the measured level is greater than the 95% percentile level in the control population.
- 8. (Original) The method of claim 1, wherein the patient is not known to have a lysosomal storage disorder before the measuring step.
- 9. (Original) The method of claim 1, wherein the patient is an infant less than one year old.
- 10. (Original) The method of claim 1, wherein the patient is a fetus and the sample is a fetal blood sample.
- 11. (Amended) The method of claim 1, wherein a change in the first level of the saposin indicates progression or regression of the disorder in the patient that is known to have a lysosomal storage disorder wherein the patient is known to have a lysosomal storage disorder and the level of the saposin indicates progression of the disorder.
- 12. (Amended) The method of claim 1, wherein a change in the first level of the saposin indicates a response to treatment of the lysosomal storage disorder in the patient that being treated for the lysosomal storage disorder. wherein the patient is known to have a lysosomal storage disorder, and is being treated for the disorder, and the level of the saposin indicates response to treatment.
- 13. (Amended) The method of claim 1, wherein the <u>first saposin or second saposin</u> is selected from the group consisting of saposin A, <u>saposin B</u>, <u>saposin C</u>, <u>and saposin D</u>, prosaposin, <u>and mRNA encoding prosaposin, and a combination thereof.</u>
- 14. (Amended) The method of claim 1, wherein the saposin is selected from the group consisting of saposin A, saposin C, or saposin D.
- 15. (Amended) The method of claim 1, wherein the measuring step comprises detecting binding between a saposin polypeptide and an antibody.
- 16. (Original) The method of claim 15, wherein the antibody is a monoclonal antibody.
- 17. (Original) The method of claim 15, wherein the antibody is immobilized to a solid phase.

- 18. (Amended) The method of claim 1, wherein the lysosomal storage <u>disorder</u> order is selected from the group consisting of cystinosis, Fabry's disease, Niemann-Pick disease, Pompe's disease, and Wolman disease, and a combination thereof.
- 19. (Original) The method of claim 1, further comprising informing the patient or a parent or guardian thereof of the presence of the lysosomal storage disorder.
- 20. (Amended) The method of claim 1, further comprising determining a treatment program based on the measurement of the first level of the first saposin.
- 21. (Withdrawn From Consideration)
- 22. (Withdrawn From Consideration)
- 23. (Withdrawn From Consideration)
- 24. (Withdrawn From Consideration)
- 25. (Withdrawn From Consideration)
- 26. (Withdrawn From Consideration)
- 27. (Withdrawn From Consideration)
- 28. (Withdrawn From Consideration).
- 29. (Withdrawn From Consideration)
- 30. (Withdrawn From Consideration)
- 31. (Withdrawn From Consideration)
- 32. (Withdrawn From Consideration)
- 33. (Withdrawn From Consideration)
- 34. (Withdrawn From Consideration)

- 35. (Withdrawn From Consideration)
- 36. (Amended) A method of monitoring treatment of a lysosomal storage disease in a patient, comprising:

determining a <u>pre-treatment</u> baseline level of a saposin in a tissue sample from the patient with a lysosomal storage disorder before treatment with an agent;

determining a post-treatment baseline level of the saposin in a sample from the patient with the lysosomal storage disorder after treatment with the agent; and

comparing a the pre-treatment baseline level of the saposin in a tissue sample from the patient obtained after treatment with the agent; agent with the baseline level, and with the post-treatment baseline level of the saposin, wherein

- (i) the sample is a plasma, serum, whole blood, urine, amniotic fluid sample, or a mixture of;
- (ii) saposin is selected from the group consisting of saposin A, saposin B, saposin C, saposin D, prosaposin, mRNA encoding prosaposin, and a combination thereof; and
- (iii) a reduction in the <u>post-treatment baseline</u> level after treatment relative to the <u>pre-treatment</u> baseline level indicates a positive treatment outcome.
- 37. (Withdrawn From Consideration)
- 38. (Withdrawn From Consideration)